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EXAMINER	
KATCHEVES, KONSTANTINA T	
ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/826,909

Applicant(s)

MOECKEL ET AL.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 26-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-51, 54, 62, 66 and 67 is/are rejected.
- 7) ☒ Claim(s) 52, 53, 55-61 and 63-65 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

New claims 26-67 are pending in the present application. This Office action is in response to the paper filed 15 March 2004 wherein claims 1-25 were cancelled and claims 26-67 were presented.

#### ***Response to Amendment***

The rejections of claims 1-16 set forth in the Office action mailed 7 May 2003 are moot in view of the cancellation of these claims in the amendment filed 15 March 2004. Any arguments made in response to the rejection of these claims in the most recent amendment will be addressed insofar as it relates to new claims 25-67.

#### ***New Grounds of Rejection Necessitated by Applicant's Amendment***

##### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The written description requirement is established by 35 U.S.C. 112, first paragraph which states that the: “*specification* shall contain a written description of the invention. . . .[emphasis added].” A specification must convey to one of skill in the art that “as of the filing date sought, [the inventor] was in possession of the invention.” See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in “possession” of the invention claimed by describing the invention with all of its claimed limitations “by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.” See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The present claims are drawn to: (1) polynucleotides having 90%, 95% and 97% identity to the polynucleotide of SEQ ID NO:1; (2) polynucleotides of SEQ ID NO:1 which comprise at least 15 consecutive nucleotides; (3) polynucleotides of SEQ ID NO:1 which comprise nucleotides 232-1161 identity to the amino acid sequence or nucleic acid sequence of SEQ ID NO:1; and (4) polynucleotides encoding a polypeptide which is at least 90%, 95%, 97% and 99% identical to the polypeptide of SEQ ID NO:2. The claims also recite vectors and bacteria comprising the polynucleotides claimed. Applicant proposes that the prior rejection made over claims 1-16 are moot because these claims are drawn to claims having greater degrees of identity with SEQ ID Nos:1 and 2. This argument is not persuasive for the following reasons.

These claims read on a broad genus of polynucleotides. According to Applicant’s claims, these sequences possess the activity of the transcription regulator LysR2. However, neither the claims nor the specification as filed indicate what distinguishing attributes the members of the claimed genus of polynucleotides share. The specification and claims do not place any limit on

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the number of substitutions, deletions, insertions and/or additions that may be made to the claimed polynucleotides. It is only required that the nucleotide sequence maintain a some identity to SEQ ID NO:1 or the polypeptides they encode share some degree of homology to SEQ ID NO:2. Moreover, the structural characteristics of the broad genus of polynucleotides embraced by Lysr2 have not sufficiently been defined, and a single example of SEQ ID NO:1 and the polypeptide of SEQ ID NO:2, encoded by SEQ ID NO:2, fail to correct this deficiency. Thus, the scope of the claims includes numerous structural variants. The specification teaches and the claims recite that the sequences possess the activity of the transcription regulator, LysR2. However, no structural features are taught for these sequences that define or are required for the activity of LysR such that one of skill in the art would not be able to determine whether Applicant had possession of such a vast number of polynucleotides; not to mention which consecutive 15 nucleic acids are required to distinguish LysR2.

Therefore, there are no common structural attributes shared among the members of the claimed genus of polypeptides that would allow one of skill in the art to clearly distinguish the members of this genus. The general knowledge and level of skill in the art do not supplement the omitted description. The specification neither discloses any of these variant, modifications or fragments claimed nor does it provide any teachings as to how the structures of these sequences relate to their function. Thus, the specification does not describe the complete structure of a representative number of species. The specification also fails describe a representative number of species in terms of partial structure and relevant identifying characteristics. Absent teachings and guidance as to the structure-function relationship of these molecules, the specification does not describe the claimed recombinant DNA molecules in such full, clear, concise and exact terms so

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as to indicate that Applicant had possession of these molecules at the time of filing of the present application.

Claim 51 is broadly drawn to an isolated coryneform bacterium, which expressed a decreased amount of the product of the *lysR2* gene. This is a broad genus of organisms for which the specification fails to provide adequate description. The bacterium of the claim embraces claims with undefined modifications, mutations or conditions so long as the *lysR2* gene product is decreased. This would include any coryneform bacterium, which had been exposed to modifications or mutations, or conditions which were lethal to the bacterium. Therefore, this broad genus of coryneform bacteria such that one of skill in the art could not reasonably conclude that Applicant was in possession of the invention claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 54, 62, 66 and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 54 and 62 recite the limitation “start codon” twice. It is unclear if this is a typographical error or whether the second “start codon” should have been another limitation.

Claims 66 and 67 are vague and indefinite because the language “compared to an unmodified starting strain” is found in parenthesis. It is unclear whether this is intended to be an actual limitation to the claims. The parenthesis sets off this phrase from the rest of the claim.

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*Allowable Subject Matter*

Claims 52,53,55-61 and 63-65 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves



JAMES KETTER  
PRIMARY EXAMINER